

## REMARKS

### In the Claims:

Claims 1, 3, 5-7 and new claims 23-25 are in the application. Claims 2 and 4 are cancelled. Claims 8-22 are withdrawn.

Claims 1 and 3 are amended herein for purposes of increasing grammatical clarity and to be consistent with comments made herein. The term "monocyte" has been added to describe "cell culture"; and the term "transcriptional" has been added to describe the product "from the cell culture" (also added). No new matter has been added by these amendments and support may be found respectively at [0037] for "monocyte"; [0009] for induction of "transcriptional" products; and [0037]-[0041] for "from the cell culture".

Claim 1 is also amended herein to incorporate the limitations of claim 2 and to add the step of selecting a maturation stage with an acceptable concentration of marker and a most potent induction activity. Support for these amendments may be found at [0017], [0034] and [0041].

Claim 3 was amended to incorporate the limitations of claim 4 and to add the step of selecting a maturation stage with an acceptable concentration of marker and a most potent induction activity. Again, support for these amendments may be found at [0017], [0034] and [0041].

Claim 5 is amended herein for purposes of correcting a spelling error. Specifically, claim 5 was objected to because the term "polysaccharides" was misspelled as "polysaccarides". Claim 5 has also been amended to change dependency from claim 4 to claim 3.

### Claim Objections

Claim 5 was objected to because it "recites 'polysaccarides' which should be spelled 'polysaccharides'." Page 2 of the Office action mailed 6/19/06. Accordingly, claim 5

has been amended to correct this spelling error. Applicants respectfully request that the object be withdrawn.

**Claim Rejections - 35 U.S.C. § 112, ¶ 1:**

Claims 1-7 stand rejected under 35 U.S.C. § 112, ¶ 1, as allegedly failing to satisfy the enablement requirement. In particular, the Office action reviews the Wands factors and concludes that “while being enabling for THP-1 cells, [the specification] does not reasonably provide enablement for all cells.” Page 3 of the Office action mailed 6/19/06.

Applicants have amended their independent claims to clarify that cell cultures required to practice the invention are monocyte lines. Similarly, new claim 24 requires the cells culture to be a monocyte or macrophage cell culture. As stated earlier, no new matter has been added by these amendments and support may be found at [0037].

Accordingly, no experimentation is needed to practice the invention as currently claimed. Applicants have overcome this ground of rejection and respectfully request that it be withdrawn.

**Claim Rejections - 35 U.S.C. § 103(a)**

Claims 1-7 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Seidler-Lozykowska et al. in view of Rininger et al. or Dou et al. in view of Rininger et al. In particular, the Office action alleges that “[o]ne of ordinary skill in the art would have been motivated to harvest Echinacea at different growth stages to ascertain its immunopotentiality on macrophage cells in order to assess immuno-function of the plant at different stages.” Page 7 of the Office action mailed 6/19/06.

Applicants respectfully disagree. According to Section 2142 of the MPEP:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the

art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

### **1. Suggestion or motivation to combine references**

Applicants respectfully submit that the Office action fails to set forth a *prima facie* case of obviousness. In particular, the first of the criteria required to establish *prima facie* obviousness is not met as to combining Seidler-Lozykowska et al. and Rininger et. al. "There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). However, according to one case, the level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999). Therefore, the first two points are discussed below.

#### **a. The nature of the problem to be solved**

The nature of the problem to be solved relates to determining optimal harvest time to augment immune-stimulatory activity at a standard biomarker level (see Abstract and claims of current application). Prior to the applicants' present application, the state of the technology was such that standardization of Echinacea products was based on levels of biomarker compounds. Applicants' specification at [0002]. Seidler-Lozykowska et al. had studied Echinacea plants harvested at various growth stages for biomarker levels. See Abstract and page 9 of Seidler-Lozykowska. Also, studies had been published discussing the variation in efficacy or pharmacological properties of

Echinacea materials, such as Rininger et al. and Barrett (prior art of record, but not relied upon in the Office action). Until applicants' disclosure, no reference (or combination of references) taught a method for standardizing an *Echinacea* biomarker level and identifying a material that augments an immune stimulatory response based on harvest window.

**b. Teachings of the prior art**

Neither Seidler-Lozykowska et al. nor Rininger et al. suggest or motivate one to combine these references. Seidler-Lozykowska et al. are concerned with defining the best harvest times base as related to maximizing concentration of polyphenolic acids. (See Abstract and page 9 of Seidler-Lozykowska). Seidler-Lozykowska does not suggest or motivate one to look for other parameters that may intersect with, or complement, polyphenolic acid concentration and the efficacy of Echinacea. Rininger et al. are not concerned at all with harvest time, but seek to explain the variability of Echinacea raw materials and commercially available products. (See Rininger Abstract) Rininger does not suggest or motivate one to look to combine any reference that addresses the issue of *Echinacea* harvest time.

Simiarly, Dou et al do not discuss optimal harvest time. Even though the reference states that, "[t]he content of chicoric acid and yield were the highest in the overground part of *E. purpurea* before and after the bloomy stage" (Abstract of Dou et al.), the term "optimal" is generally understood to mean "most desirable or satisfactory". Merriam Webster's Collegiate Dictionary, tenth edition, 1993 (enclosed). Dou et al. literally suggest that the best chicoric acid levels may be found in plant parts of Echinacea at any time other than during bloom. They do not suggest looking for references that discuss immunostimulatory activity to determine a more specific harvest time. For the reasons stated above, Rininger does not suggest or motivate one to search for a reference such as Dou et al.

## 2. Reasonable expectation of success

The second of the criteria required to show *prima facie* obviousness, that there be reasonable expectation of success, is not satisfied by combining either Seidler-Lozykowska et al. or Dou et al. with Rininger et al. because Rininger et al. specifically state that *Echinacea* extracts, etc. did not produce immunostimulatory activity. The Office action states that “Rininger et al. analyzed the production of TNF- $\alpha$ , IL-1 $\alpha$ , IL-1 $\beta$ , IL-6, IL-10 and nitric oxide from macrophage cells upon contact with several products of *Echinacea* including standardized extracts, whole plant parts, whole plant material, juice and phenolic compounds.” Page 6 of Office Action mailed 6/19/06. In fact, Rininger states that, “*Echinacea* extracts standardized to [biomarkers] phenolic acid or echinocaside content and fresh pressed juice preparations were found to be inactive as immunostimulatory agents, but did display, to varying degrees, anti-inflammatory and antioxidant properties.” See pages 1 and 10 of the website version of Rininger et al. in *Journal of Leukocyte Biology* 2000; 68:503-510. Rininger teaches away from the ability to find immunostimulatory activity from *Echinacea* materials prepared by methods other than their stimulated digestion protocol to emulate oral dosing. Abstract and pages 9-10 of Rininger.

Applicants’ current claims and the claims as originally examined, include the step of adding a preparation to a cell culture. The term “preparation” is defined in the specification at [0014] to mean “*Echinacea* plant products that result from the dehydrating and/or powdering of plant material or from the chemical extraction of plant material.” Based on the teachings of Rininger, there would not be reasonable expectation of success in combining either Seidler-Lozykowska et al. or Dou et al. because Rininger teaches only that “through a simulated digestive protocol, the immunostimulatory activity was detected” and that, “cells with *Echinacea purpurea* herb test material dissolved in traditional solvents for in vitro studies, such as dimethyl sulfoxide, were inactive for production of TNF- $\alpha$  and NO as activation biomarkers.” Page 5 of the website version of Rininger.

### 3. Combined references must teach or suggest all claim limitations

Further, the third criteria for establishing a *prima facie* case of obviousness is not satisfied because neither the combination of Seidler-Lozykowska et al. and Rininger et al. nor Dou et al. and Rininger et al. teach or suggest all of the claim limitations. For example, the limitation of independent claims 1 and 3 that requires, "selecting a maturation stage with an acceptable concentration of marker compound and a most potent induction activity" is absent from the combination.

As to the Rininger et al. reference, if *prima facie* obviousness were established, the reference is improperly combined with either Seidler-Lozykowska et al. or Dou et al. to render obvious the applicants' claims for two reasons. First, Rininger et al. state that their "data highlight the variability of natural products and, for *Echinacea*, could represent non-optimal harvest time, environmental conditions, or storage factors that govern production and preservation of *Echinacea*'s immunostimulatory activity," (page 7 of the website version of Rininger). This statement teaches numerous possible choices and would require each to be tried until one possibly arrived at a successful result. Rininger gives no indication of which parameters were critical and no direction as to which of the possible choices is likely to be successful. See MPEP 2145. Second, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) See MPEP 2141.02. As mentioned above, Rininger teaches away from the claimed invention by teaching only that "through a simulated digestive protocol, the immunostimulatory activity was detected" and that, "cells with *Echinacea purpurea* herb test material dissolved in traditional solvents for in vitro studies, such as dimethyl sulfoxide, were inactive for production of TNF- $\alpha$  and NO as activation biomarkers." Page 5 of the website version of Rininger. See also pages 1 and 10 of Rininger.

Thus, the Office action fails to set forth a *prima facie* case of obviousness. Indeed, one of ordinary skill in the art would not be motivated to use the teachings of Rininger et al. with either Seidler-Lozykowska et al. or Dou et al. to harvest *Echinacea* at different

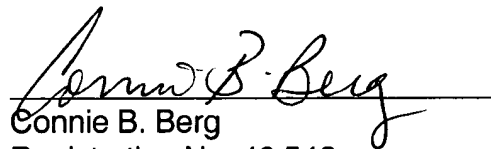
growth stages to ascertain its immunopotentiality on macrophage cells in order to assess immuno-function of the plant at different stages. Applicants have overcome this ground of rejection and respectfully request that it be withdrawn.

### SUMMARY

Applicants believe that claims 1, 3, 5-7 and 23-25 are patentable. If fees are required so that this response be considered timely filed, the Commissioner is hereby authorized to charge such additional fees to deposit account no. 01-1793. The Examiner is invited to contact the undersigned attorney for Applicants via telephone if such communication would expedite allowance of this application.

Date: September 19, 2006

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Connie B. Berg", is written over a horizontal line.

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- tice of taking advantage of opportunities or circumstances often with little regard for principles or consequences — **op-por-tun-ist** \-'tū-nist, -'tū- n or adj
- op-por-tu-nis-tic** \-'tū-nis-tik, -'tū- n adj (1892): taking advantage of opportunities as they arise: as a: exploiting opportunities with little regard to principle or consequences (a politician considered ~) b: feeding on whatever food is available (~ feeders) c: being or caused by a usu. harmless microorganism that can become pathogenic when the host's resistance is impaired (~ infections) — **op-por-tu-nis-ti-cal-ly** \-'tū-k(a)-lē adv
- op-por-tu-ni-ty** \-'pōr-'tū-nə-tē, -'tū- n, pl -ties (14c) 1: a favorable juncture of circumstances (the halt provided an ~ for rest and refreshment) 2: a good chance for advancement or progress
- opportunity cost** n (1911): the cost of making an investment that is the difference between the return on one investment and the return on an alternative
- op-pos-able** \-'pōz-'ə-bəl adj (1667) 1: capable of being opposed or resisted 2: capable of being placed against one or more of the remaining digits of a hand or foot (the ~ human thumb) — **op-pos-abil-ity** \-'pōz-'ə-bi-lə-tē n
- op-pose** \-'pōz- vi **op-posed**; **op-posing** [F *opposer*, fr. L *opponere* (perf. indic. *opposui*), fr. ob- against + *ponere* to place — more at **OB-**POSITION] (1579) 1: to place opposite or against something 2: to place over against something so as to provide resistance, counterbalance, or contrast 3: to offer resistance to — **op-poser** n
- syn** **OPPOSE**, **COMBAT**, **RESIST**, **WITHSTAND** mean to set oneself against someone or something. **OPPOSE** can apply to any conflict, from mere objection to bitter hostility or warfare (*opposed the plan*). **COMBAT** stresses the forceful or urgent countering of something (*combat disease*). **RESIST** implies an urgent recognition of a hostile or threatening force and a positive effort to counteract or repel it (*resisting temptation*). **WITHSTAND** suggests a more passive resistance (*trying to withstand peer pressure*).
- op-posed** \-'pōzd adj (1596): set or placed in opposition: **CONTRARY** (with politicians, as ~ to soap, you cannot return what you have bought) — **Felix G. Rohatyn**
- op-pose-less** \-'pōz-'ləs adj (1605) **archaic**: **IRRESISTIBLE**
- op-po-si-ble** \-'pōz-'sə-bəl, -'sə-səb adj [ME, fr. MF, fr. L *oppositus*, pp. of *oppone*] (14c) 1: a: set over against something that is at the other end or side of an intervening line or space (~ interior angles) (~ ends of a diameter) b: situated in pairs on an axis with each member being separated from the other by half the circumference of the axis (~ leaves) — compare **ALTERNATE** 2 a: occupying an opposing and often antagonistic position (~ sides of the question) b: diametrically different (as in nature or character) (~ meanings) 3: contrary to one another or to a thing specified: **REVERSE** (gave them ~ directions) 4: being the other of a pair that are corresponding or complementary in position, function, or nature (members of the ~ sex) 5: of, relating to, or being the side of a baseball field that is near the first base line for a right-handed batter and near the third base line for a left-handed batter — **op-po-si-ble-ly** adv — **op-po-si-ble-ness** n
- syn** **OPPOSITE**, **CONTRADICTORY**, **CONTRARY**, **ANTITHETICAL** mean being so far apart as to be or seem irreconcilable. **OPPOSITE** applies to things in sharp contrast or in conflict (*opposite views on foreign aid*). **CONTRADICTORY** applies to two things that completely negate each other so that if one is true or valid the other must be untrue or invalid (*made contradictory predictions about whether the market would rise or fall*). **CONTRARY** implies extreme divergence or diametrical opposition (*contrary assessments of the war situation*). **ANTITHETICAL** stresses clear and unequivocal diametrical opposition (a law that is *antithetical* to the very idea of democracy).
- opposite** n (15c) 1: something that is opposed to some other often specified thing 2: **ANTONYM** 3: **ADDITIVE INVERSE**: esp: the additive inverse of a real number
- opposite** adv (1667): on or to an opposite side
- opposite** prep (1758) 1: across from and usu. facing or on the same level with (sat ~ each other) 2: in a role complementary to (played ~ the leading man in the comedy)
- opposite** number n (1906): a member of a system or class who holds relatively the same position as a particular member in a corresponding system or class: **COUNTERPART**
- op-po-si-tion** \-'pō-'zī-shən n (14c) 1: a configuration in which one celestial body is opposite another in the sky or in which the elongation is near or equal to 180 degrees 2: the relation between two propositions having the same subject and predicate but differing in quantity or quality or both 3: an act of setting opposite or over against: the condition of being so set 4: hostile or contrary action or condition 5 a: something that opposes; *specif*: a body of persons opposing something b *often cap*: a political party opposing and prepared to replace the party in power — **op-po-si-tion-al** \-'zī-sh-nəl, -'zī-sh-nəl adj
- op-po-si-tion-ist** \-'zī-sh(n)-'ist n (1773): a member of an opposition — **oppositionist** adj
- op-press** \-'pres- vi [ME, fr. MF *oppresser*, fr. L *oppressus*, pp. of *opprimere*, fr. ob- against + *primere* to press — more at **OB-**PRESS] (14c) 1: **archaic**: **SUPPRESS** b: to crush or burden by abuse of power or authority 2: to burden spiritually or mentally: weigh heavily upon **syn** **see WRONG** — **op-pres-sor** \-'pre-sər n
- op-pres-sion** \-'pre-shən n (14c) 1: a: unjust or cruel exercise of authority or power b: something that oppresses esp. in being an unjust or excessive exercise of power 2: a sense of being weighed down in body or mind: **DEPRESSION**
- op-pres-sive** \-'pre-siv adj (ca. 1677) 1: unreasonably burdensome or severe (~ legislation) 2: **TYRANNICAL** 3: overwhelming or depressing to the spirit or senses (an ~ climate) **syn** **see ONEROUS** — **op-pres-sive-ly** adv — **op-pres-sive-ness** n
- op-pro-bri-ous** \-'prō-brē-'əs adj (14c) 1: expressive of opprobrium: **SCURRILOUS** (~ language) 2: deserving of opprobrium: **INFAMOUS** — **op-pro-bri-ous-ly** adv — **op-pro-bri-ous-ness** n
- op-pro-bri-um** \-'brē-əm n [L, fr. *opprobriare* to reproach, fr. ob- in the way of + *probrum* reproach; akin to L *pro* forward and to L *ferre* to carry, bring — more at **OB-**FOR, **BEAR**] (1656) 1: something that brings disgrace 2 a: public disgrace or ill fame that follows from conduct considered grossly wrong or vicious b: **CONTEMPT**, **REPROACH**
- op-pugn** \-'pyün, -'ä- vi [ME, fr. L *oppugnare*, fr. ob- against + *pugnare* to fight — more at **OB-**PUNGE] (15c) 1: to fight against 2: to call in question — **op-pugn-er** n
- Ops** \-'aps n [L]: the Roman goddess of abundance and the wife of Saturn
- op-sin** \-'ap-sən n [prob. fr. *rhodopsin*] (1951): any of various colorless proteins that in combination with retinal or a related prosthetic group form a visual pigment (as rhodopsin) in a reaction which is reversed by light
- opsis** n **comb form**, pl **-opses** or **-opsides** [NL, fr. Gk, fr. *opsis* appearance, vision]: structure resembling a (specified) thing (*caryopsis*)
- op-son-ic** \-'ap-sä-nik adj (1903): of, relating to, or involving opsonin
- op-so-nin** \-'ap-sä-nən n [L *opsonare* to buy provisions, cater (fr. Gk *opsōnein*) + E *-in* — more at **OLIGOPSONY**] (1903): an antibody of blood serum that makes foreign cells more susceptible to the action of the phagocytes
- opsy** n **comb form** [Gk *-opsis*, fr. *opsis*]: examination (*necropsy*)
- opt** \-'apt vi [F *opter*, fr. L *optare*] (1877): to make a choice; esp: to decide in favor of something (~ed for a tax increase — Tom Wicker)
- op-ta-tive** \-'ap-tə-tiv adj (15c) 1 a: of, relating to, or constituting a verbal mood that is expressive of wish or desire b: of, relating to, or constituting a sentence that is expressive of wish or hope 2: expressing desire or wish — **optative** n — **op-ta-tive-ly** adv
- op-tic** \-'ap-tik adj [ME, fr. MF *optique*, fr. ML *opticus*, fr. Gk *optikos*, fr. *opsēsthai* to be going to see; akin to Gk *opsis* appearance, *ops* eye — more at **EYE**] (14c): of or relating to vision or the eye
- optic** n (1600) 1: **EYE** 2 a: any of the elements (as lenses, mirrors, or light guides) of an optical instrument or system — usu. used in pl. b: an optical instrument
- op-ti-cal** \-'ap-ti-kəl adj (1570) 1: of or relating to the science of optics 2 a: of or relating to vision: **VISUAL** b: **VISIBLE** (~ wave-length) c: of, relating to, or being objects that emit light in the visible range of frequencies (an ~ galaxy) d: using the properties of light to aid vision (an ~ instrument) 3 a: of, relating to, or utilizing light esp. instead of other forms of energy (~ microscopy) b: involving the use of light-sensitive devices to acquire information for a computer (~ character recognition) 4: of or relating to optical art — **op-ti-cal-ly** \-'k(a)-lē adv
- optical activity** n (1877): ability of a chemical substance to rotate the plane of vibration of polarized light to the right or left
- optical art** n (1964): nonobjective art characterized by the use of straight or curved lines or geometric patterns often for an illusory effect (as of motion)
- optical bench** n (1883): an apparatus that is fitted for the convenient location and adjustment of light sources and optical devices and that is used for the observation and measurement of optical phenomena
- optical disk** n (1980): a disk with a plastic coating on which information (as music or visual images) is recorded digitally (as in the form of tiny pits) and which is read by using a laser
- optical fiber** n (1962): a single fiber-optic strand
- optical glass** n (1840): flint or crown glass of well-defined characteristics used esp. for making lenses
- optical illusion** n (1794): **ILLUSION** 2a(1)
- optically active** adj (1885): capable of rotating the plane of polarization of light to the right or left — used of compounds, molecules, or atoms
- optical rotation** n (1895): the angle through which the plane of vibration of polarized light that traverses an optically active substance is rotated
- optic axis** n (1664): a line in a doubly refracting medium that is parallel to the direction in which all components of plane-polarized light travel with the same speed
- optic chiasma** n (1872): the X-shaped partial decussation on the undersurface of the hypothalamus through which the optic nerves are continuous with the brain — called also *optic chiasm*
- optic cup** n (ca. 1885): the optic vesicle after invaginating to form a 2-layered cup from which the retina and pigmented layer of the eye will develop — called also *eyecup*
- optic disk** n (ca. 1890): **BLIND SPOT** 1a
- op-ti-cian** \-'ap-ti-shən n (1687) 1: a maker of or dealer in optical items and instruments 2: a person who reads prescriptions for visual correction, orders lenses, and dispenses spectacles and contact lenses — compare **OPHTHALMOLOGIST**, **OPTOMETRIST**
- optic lobe** n (1854): either of two prominences of the midbrain concerned with vision
- optic nerve** n (1615): either of the pair of nerves that comprise the 2d pair of cranial nerves, arise from the ventral part of the diencephalon, supply the retina, and conduct visual stimuli to the brain — see **EYE** illustration
- optics** \-'ap-tiks n pl but sing in constr (1579): a science that deals with the genesis and propagation of light, the changes that it undergoes and produces, and other phenomena closely associated with it
- optic vesicle** n (ca. 1885): an evagination of each lateral wall of the embryonic vertebrate forebrain from which the nervous structures of the eye develop
- op-ti-mal** \-'ap-tə-məl adj (1890): most desirable or satisfactory: **OPTIMUM** — **op-ti-mal-ly** \-'ap-tə-'mə-lə-tē n — **op-ti-mal-ly** \-'mə-lē adv
- op-ti-mi-sa-tion**, **op-ti-mise** Brit var of **OPTIMIZATION**, **OPTIMIZE**
- op-ti-mism** \-'ap-tə-mi-zəm n [F *optimisme*, fr. L *optimum*, n, best, fr. neut. of *optimus* best; akin to L *ops* power — more at **OPULENT**] (1759) 1: a doctrine that this world is the best possible world 2: an inclination to put the most favorable construction upon actions and events or to anticipate the best possible outcome — **op-ti-mist** \-'mɪst n — **op-ti-mis-tic** \-'ap-tə-'mɪs-tik adj — **op-ti-mis-ti-cal-ly** \-'ti-k(a)-lē adv
- Op-ti-mist** \-'ap-tə-mɪst n [*Optimist (Club)*] (1911): a member of a major international service club
- op-ti-mi-za-tion** \-'ap-tə-mə-'zā-shən n (1857): an act, process, or methodology of making something (as a design, system, or decision) as fully perfect, functional, or effective as possible; *specif*: the mathematical procedures (as finding the maximum of a function) involved in this
- op-ti-mize** \-'ap-tə-mɪz- vi -mized; -miz-ing (1857): to make as perfect, effective, or functional as possible — **op-ti-miz-er** \-'mɪ-zər n
- op-ti-mum** \-'ap-tə-məm n, pl -ma \-'mə- also -mums [L] (1879) 1